



PARI GmbH Spezialisten für effektive Inhalation
Postfach 1551 · 82317 Starnberg

04 March 2019

Urgent Field Safety Notice
Batch Recall of PARI LC SPRINT Tracheo (Article# 023G1080) Lot # 1000061062

Dear Customer,

We would like to inform you that PARI GmbH has decided to recall the following batch of our PARI LC SPRINT Tracheo from the market because of a picking error:

Product Name	Article Number	Lot number
PARI LC SPRINT Tracheo	023G1080	1000061062

Description of problem and patient risk:

The affected batch includes instead of the LC tracheal adapter a wrong tracheal adapter which has no exhalation holes. Hence, a patient with a blocked tracheal cannula would not be able to exhale during therapy and would experience dyspnoea in a worst case. Therefore, PARI has decided to recall this batch.

Actions to be taken:

Please check your inventory and fill out the enclosed Acknowledgement Form and return it to PARI GmbH using the contact details as given in the attached form. PARI will issue a credit for the products returned in connection with this notification.

Please acknowledge the receipt of this Field Safety Notice and return it to us.

Please distribute this Field Safety Notice within your organization and ensure that all relevant persons have been informed. If you or your facility has distributed these affected products to other persons or facilities, please promptly forward a copy of this Field Safety Notice.

PARI GmbH apologizes for any inconvenience this has caused and thank you in advance for your support and your cooperation.

If you have any questions regarding this notification, please do not hesitate to contact us.

PARI GmbH Spezialisten für effektive Inhalation
Geschäftsführer: Dr. Davia Viellechner
Registergericht München: HRB 66 609
Finanzamt Fürstfeldbruck für Körperschaft
St.-Nr.: 117/116/01203
USt-IdNr.: DE 128 241 619

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Kto 130 980
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BIC HYVEDEMMXXX



The relevant competent authorities have been informed about this Field Safety Action.

Best regards,

[Redacted signature]



Acknowledgement of Receipt of the Field Safety Notice

Please return this form by Fax: +49-8151-279101

We have acknowledge the receipt and notice of this this Field Safety Notice dated 4 March 2019 regarding the batch recall of the PARI LC SPRINT Tracheo (Article#. 023G1080) with Lot# 1000061062.

The Field Safety Notice has been shared within our organization and we have ensured that all relevant persons have been informed. In case we have distributed the affected products to other persons or facilities, we have forwarded a copy of this Field Safety Notice and Response Form.

Please indicate your inventory of products concerned by this Field Corrective Action (even if zero):

Product Name	Article Number	Lot Number	Inventory
PARI LC SPRINT Tracheo	023G1080	1000061062	

Company: _____

Name: _____

Telephone number: _____

Date and Signature : _____